

Attorney Docket No.: **UMD-0033**
Inventors: **Rameshwar and Gascon**
Serial No.: **10/628,066**
Filing Date: **July 25, 2003**
Page 4

REMARKS

Claims 1, 2, 6, 12-14, 18 and 20 are pending in this application. Claims 1, 2 and 6 have been allowed. Claims 12-14, 18 and 20 have been rejected. Claim 13 has been amended. Claims 12 and 20 have been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Election/Restriction Requirement Under 35 U.S.C. §121

Applicants acknowledge the withdrawal of the species election and search of the species recited in the claims.

II. Rejection of Claims Under 35 U.S.C. §112

Claims 12 and 20 have been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, it is suggested that the limitation "the molecule specifically hybridizes to a coding sequence comprising SEQ ID NO:15" makes the property boundary of the claims vague and confusion. Applicants respectfully disagree. However, in an earnest effort to facilitate the prosecution of the present application, Applicants have canceled claims 12 and 20. It is therefore respectfully requested that this rejection be withdrawn.

Claims 12-14, 18 and 20 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It is suggested that the rejected claims are drawn to a genus of DNA molecules with various degrees of variations from SEQ ID NOS:1, 14, or 15. It is suggested that the

Attorney Docket No.: **UMD-0033**
Inventors: **Rameshwar and Gascon**
Serial No.: **10/628,066**
Filing Date: **July 25, 2003**
Page 5

skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, given that the specification has only described SEQ ID NO:1 and 14. Applicants respectfully disagree.

Because claim 12 has been canceled, Applicants will address this rejection with respect to claim 13 and claims dependent therefrom. Examples 7 and 8 clearly provide the skilled artisan with the necessary guidance as to the particular portion of SEQ ID NO:1 which must be conserved in order to have the recited function as in claim 13. In particular, page 55 (lines 28-31) indicates that an available cAMP response element (CRE), e.g., as listed in Table 5, is required for optimum promoter activity. Accordingly, in an earnest effort to clarify the structural element of SEQ ID NO:1 required to achieve the recited promoter activity, Applicants have amended claim 13 (as supported by the disclosure at page 55, lines 28-31, and Table 5), to indicate that the 500 nucleotides of SEQ ID NO:1 includes a cAMP response element having the sequence of TGACGTCT or TTGCGTCA. In light of this clarification, it is respectfully submitted that Applicants have provided a distinguishing characteristic of the claimed genus to satisfy the written description requirement. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

III. Rejection of Claims Under 35 U.S.C. §102

Claims 12-14, 18 and 209 have been rejected under 35 U.S.C. 102(b) as being anticipated by WO 87/07643 (A1 of IDS). In so far as claims 12-14, 18 and 20 have been interpreted as being drawn to a DNA molecule similar to SEQ ID NO:1, 14, or 15, the Examiner

Attorney Docket No.: **UMD-0033**
Inventors: **Rameshwar and Gascon**
Serial No.: **10/628,066**
Filing Date: **July 25, 2003**
Page 6

suggests that WO 87/07643 teaches a DNA molecule that hybridizes to SEQ ID NO:15. It is further suggested that because claim 13 recites "a fragment of at least 500 nucleotides of SEQ ID NO:1," it is unclear whether the claimed invention is limited to at least 500 contiguous nucleotides of SEQ ID NO:1 or at least 500 nucleotides that has a part of SEQ ID NO:1. It is suggested that since the claimed structure and the DNA structure taught by WO 87/07643 are the same, the DNA structure inherently has promoter activity, especially given that WO 87/07643 teaches 5' untranslated region at Fig. 1. Applicants respectfully disagree with this rejection.

As is clear from the promoter analysis disclosed in Figure 3, the "at least 500 nucleotides of SEQ ID NO:1" of claim 13 refer to at least 500 contiguous nucleotides. Accordingly, to distinguish the claimed fragment, from the prior art, Applicants have further amended claim 13, to indicate that the at least 500 nucleotides are contiguous. In so far as claim 12 has been canceled, it is respectfully submitted that the part of this rejection pertaining to claim 12 is moot.

In order for a reference to anticipate a claim, "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). MPEP §2131.

Because the cited reference fails to teach the nucleotide fragment as claimed, this reference cannot be held to anticipate the present invention. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

Attorney Docket No.: **UMD-0033**
Inventors: **Rameshwar and Gascon**
Serial No.: **10/628,066**
Filing Date: **July 25, 2003**
Page 7

IV. Allowable Subject Matter

Applicants acknowledge the allowance of claims 1, 2, and 6.

V. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



Jane Massey Licata
Registration No. 32,257

Date: **February 26, 2007**

Licata & Tyrrell P.C.
66 E. Main Street
Marlton, New Jersey 08053

(856) 810-1515